

DECLARATION AND POWER OF ATTORNEY

As the below named inventors, we hereby declare that:

Our residences, post office addresses and citizenships are as stated below next to our names.

We believe that we are the original, first and joint inventors of the subject matter which is claimed and for which a patent is sought on the invention entitled CATHETER HAVING A SOFT DISTAL TIP, the specification of which is attached hereto.

We hereby state that we have reviewed and understand the contents of the above-identified specification, including the claims, as amended by or any amendment(s) referred to above.

We acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, §1.56(a).

We hereby claim foreign priority benefits under Title 35, United States Code §119 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed:

Prior Foreign Application(s)

We hereby claim the benefit under Title 35, United States Code, §120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, §112, we acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §1.56(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application.

We hereby declare that all statements made herein of our own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under §1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

We hereby appoint the following attorneys to prosecute this application and to transact all business in the United States Patent and Trademark Office connected therewith:

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CATHETER HAVING A SOFT DISTAL TIP

BACKGROUND OF THE INVENTION

This invention relates to the field of medical devices, and more
5 particularly to a balloon catheter having a soft distal tip.

Catheters designed for intravascular procedures such as angioplasty
have a number of design considerations. Such catheters must be able to
transmit force along the length of the catheter shaft so that the catheter can
be pushed through the patient's vasculature. However, the catheter shaft
10 must also have sufficient flexibility to allow it to track over a guidewire
through tortuous vasculature. The catheter also must be able to cross
stenosed portions of the vascular anatomy.

Prior art intravascular catheters have commonly included a soft distal
tip to prevent or minimize injury to the vessel during advancement of the
15 catheter therein. One difficulty has been forming a connection between the
soft tip and the catheter which is sufficiently strong to prevent
disengagement of the soft tip or kinking at the junction between the soft tip
and catheter shaft. Additionally, it is necessary to balance the strength of
the connection between the soft tip and the catheter shaft with the need to
20 minimize the stiffness of the distal end of the catheter. Minimizing the
stiffness of the distal end of the catheter results in improved maneuverability
of the catheter.

Accordingly, it would be a significant advance to provide a catheter

with a soft tip having improved performance. This invention satisfies these and other needs.

SUMMARY OF THE INVENTION

5 The invention is directed to an intraluminal catheter having a soft distal tip, and generally comprising an elongated catheter shaft having proximal and distal ends, at least one lumen, and a soft distal tip member secured to the distal end of the catheter having a proximal end spaced distally apart from the distal end of the catheter shaft.

10 One embodiment of the invention is a balloon catheter generally comprising an elongated catheter shaft having an inflation lumen therein, a balloon on a distal shaft section in fluid communication with the inflation lumen, and a soft distal tip member on a distal end of the catheter. In accordance with the invention, the tip member has a proximal end spaced
15 distally apart from the distal end of the catheter shaft. In one presently preferred embodiment, a distal shaft section of the balloon is bonded to the distal end of the catheter shaft, so that the balloon inflatable interior is spaced proximal to the distal end of the elongated catheter shaft. The balloon distal shaft section is also bonded to the proximal end of the tip
20 member, to thereby secure the tip member to the distal end of the catheter. The tip member typically has a lumen in fluid communication with a lumen of the catheter distal shaft section.

The distal tip member is preferably softer than the catheter shaft, to provide improved catheter maneuverability and decrease the risk of damage to the patient's vessel during advancement of the catheter therein. The tip member is typically formed of a polymeric material having a Shore Durometer hardness which is lower than the Shore Durometer hardness of the polymeric material forming at least a section of the catheter shaft. The Shore Durometer hardness of the polymeric material forming the tip member is about 35D to about 63D, preferably about 40D to about 55D. In a presently preferred embodiment, the tip member is formed of a polyether block amide polymer such as PEBAX (available from Autochem). However, the tip member may be formed of a variety of suitable materials, including polyolefin based copolymers such as a polyethylene based adhesive polymers such as an ethylene-acrylic acid copolymer which is sold commercially as PRIMACOR by Dow Chemical Co., and polyurethanes, such as polyurethane block copolymers such as PELLETHANE (a polyester based polyurethane, available from Dow Plastics).

In accordance with the invention, the tip member has a proximal end spaced distally apart from the distal end of the catheter shaft. In one embodiment, a gap exists between the distal end of the shaft and the proximal end of the tip member, and the balloon distal shaft section surrounds and extends over the gap. In another embodiment, a portion of the balloon distal shaft section or an intermediate member is disposed within

the space between the distal end of the catheter shaft and the proximal end of the tip member.

A method of forming a distal tip of the invention generally comprises positioning a proximal end of the tip member within a balloon distal shaft

5 section, so that the tip member proximal end is spaced distally apart from a distal end of a catheter shaft which is also within the balloon distal shaft section, and fusion bonding the balloon distal shaft section of the catheter shaft and the tip member. In one embodiment, the balloon material flows during fusion bonding into at least a part of the space between the proximal
10 end of the catheter shaft and the distal end of the tip member.

The catheter of the invention having a distal tip member spaced distally from the distal end of the catheter shaft has excellent crossability and trackability. The catheter has a smooth transition in stiffness along the distal end of the catheter at the distal tip member, to improve handling and
15 performance and minimize kinking. Additionally, the catheter has good tensile strength at the tip member attachment, without disadvantageously increasing the stiffness or profile of the distal end of the catheter. These and other advantages of the invention will become more apparent from the following detailed description and exemplary drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is an elevational view of a balloon catheter which embodies

features of the invention.

Fig. 2 is an enlarged, longitudinal cross sectional view of the distal end of the catheter shown in Fig. 1, taken along lines 2-2.

Fig. 3 is a cross sectional view of the catheter shown in Fig. 2, taken
5 along lines 3-3.

Fig. 4 is a cross sectional view of the catheter shown in Fig. 2, taken along lines 4-4.

Fig. 5 is a cross sectional view of the catheter shown in Fig. 2, taken along lines 5-5.

FIG. 6 is an enlarged, longitudinal cross sectional view of an alternate
10 embodiment of the catheter of the invention, having balloon shaft material between the catheter shaft and tip member.

FIG. 7 is an enlarged, longitudinal cross sectional view of an alternate
embodiment of the catheter of the invention, having an intermediate member
15 between the catheter shaft and distal tip member.

DETAILED DESCRIPTION OF THE INVENTION

Fig. 1 illustrates a balloon catheter 10 embodying features of the invention, comprising an elongated catheter shaft 11 having a proximal shaft
20 section 12 and a distal shaft section 13, a tip member 14, an inflatable balloon 15 on the distal catheter shaft section 13 having an interior 16, and an adapter 17 on the proximal catheter shaft section 12. In the embodiment

illustrated in Fig. 1, the catheter shaft 11 comprises an outer tubular member 18 having an inflation lumen 19, and an inner tubular member 21 having a guidewire receiving lumen 22 disposed within the inflation lumen 18.

Guidewire 23, illustrated in Fig. 1 within guidewire receiving lumen 22,

5 extends to port 24 in the distal end of the tip member 14. Balloon 15 has a working section 25, a proximal shaft section 26 disposed about and secured to a distal portion of the outer tubular member 18, and a distal shaft section 27.

As best illustrated in Fig. 2, showing an enlarged longitudinal cross
10 sectional view of a distal section of the catheter 10 shown in Fig. 1 taken along lines 2-2, the proximal end of the tip member 14 is spaced distally apart from the distal end of the inner tubular member 21, and thus is not in contact therewith. In the embodiment illustrated in Fig. 2, the distal end of the inner tubular member 21 is disposed distally of the inflatable interior 16
15 of the balloon. The balloon distal shaft section 27 is disposed about a distal portion of the inner tubular member 21 and a proximal portion of the tip member 14. In a presently preferred embodiment, the balloon distal shaft section 27 is secured to both the proximal portion of the inner tubular member 21 and the distal portion of the tip member 14, as for example, by
20 fusion bonding. It would be obvious to one of ordinary skill in the art that a sheath (not shown) located distally adjacent to the distal end of the balloon distal shaft section 27 could be disposed about and secured to the inner

tubular member 21 or tip member 14 in place of the distal end of the balloon distal shaft section 27.

As best illustrated in Fig. 2, tip member 14 has a lumen 28 in fluid communication with guidewire receiving lumen 22. Figs. 3, 4 and 5 illustrate transverse cross sectional views from the distal portion of the inner tubular member 21 to the proximal portion of the tip member 14 of the catheter 10, taken along lines 3-3, 4-4, and 5-5, respectively. Tip member 14 is preferably a soft tip formed of a polymeric material which is softer than the material forming at least the distal portion of the inner tubular member 21, which is secured to the balloon distal shaft section 27. The tip member 14 illustrated in Figs. 2 and 5 is formed of a single layer of a material or a blend of materials. However, the tip member 14 may be a multilayered or multisectioned member (not shown).

In the embodiment illustrated in Fig. 2, a gap 31 is between the distal end of the inner tubular member 21 and the proximal end of the tip member 14. Gap 31 is defined between and in part by a transverse surface 33 of the distal end of the inner tubular member 21 and a transverse surface 34 of the proximal end of the tip member 14. Balloon distal shaft section 27 is in surrounding relation to the distal end of the inner tubular member 21, gap 31, and the proximal end of the tip member 14, so that the balloon distal shaft section 27 extends over and in part defines gap 31. As best illustrated in Fig. 4, showing transverse cross section of the balloon distal shaft section

27 at the gap 31, the inner diameter of the balloon distal shaft section is greater than the inner diameter of the tip member 14.

In an alternative embodiment illustrated in Fig. 6, a portion 32 of the balloon distal shaft section 27 extends between the distal end of the inner tubular member 21 and the proximal end of the tip member 14. The portion 32 is in contact with the transverse surfaces 33 and 34, and has an inner surface 35 which defines a section of the guidewire receiving lumen 22. In the embodiment illustrated in Fig. 6, the inner surface 35 of the portion 32 of the balloon distal shaft section 27 is substantially axially aligned with the inner surface 36 of the tip member 14. The phrase substantially axially aligned should be understood to mean that the portion 32 of the balloon distal shaft section 27 and the tip member 14 have the same inner diameter, or similar inner diameters allowing for some slight variation in the inner surfaces 35/36. In an alternative embodiment, the portion 32 of the balloon distal shaft section 27 may fill only a portion of the space between the inner tubular member 21 and the tip member 14, so that an inner portion of the gap 31 remains (not shown).

In another embodiment illustrated in Fig. 7, intermediate member 41 is secured to and extends between the distal end of the inner tubular member 21 and the proximal end of the tip member 14. In the embodiment illustrated, the intermediate member 41 has a tubular shape with a length equal to the length of the space between the distal end of the inner tubular

member 21 and the proximal end of the tip member 14. In a presently preferred embodiment, the intermediate member 41 is formed of a polymeric material which has a Shore Durometer hardness which is lower than a Shore Durometer hardness of the inner tubular member 21 and higher than that of the tip member 14. However, the softness of the material may vary depending on the length of the bond between the balloon distal shaft section 27 and the tip member 14, and the desired use of the catheter 10. The intermediate member 41 can be made from a variety of suitable materials, such as a polyamide including a polyether block amide, and polyethylene based adhesive polymers including ethylene-acrylic acid copolymers such as PRIMACOR sold commercially by Dow Chemical Co., and polyurethanes such as PELLETHANE. The intermediate member 41 may be configured similar to the portion 32 of the balloon distal shaft section 27, as discussed above regarding the embodiment shown in Fig. 6. In the embodiment illustrated in Fig. 7, the intermediate member 41 has an inner surface substantially axially aligned with the inner surface 36 of the tip member 14 and an inner surface of the inner tubular member 21, as discussed above regarding the portion 32 of the balloon distal shaft section 27 shown in Fig. 6. The intermediate member 41, and portion 32 of balloon distal shaft section 27, preferably define annular lumens similar to those shown in Figs. 3-5.

The space is sufficiently long so that the polymeric materials forming the inner tubular member 21 and tip member 14 do not flow into contact with one

another during fusion bonding of the balloon distal shaft section 27 thereto. The length of the space (i.e., the length of gap 31, or portion 32, or intermediate member 41) between the distal end of the inner tubular member 21 and the proximal end of the tip member 14 may vary depending on the desired catheter performance, the length of the balloon distal shaft section 27 and tip member 14, and the method used to bond to tip member. The length of the space is typically about 0.05 mm to about 0.75 mm, preferably about 0.05 mm to about 0.5 mm, most preferably about 0.1 mm to about 0.3 mm. In a presently preferred embodiment, the balloon distal shaft section 27 is about 1 to about 3 mm, preferably about 1.8 to about 2.2 mm. The tip member 14 is typically about 1 to about 5 mm, preferably about 2 to about 3 mm. In the embodiment illustrated in Figs. 2, 6 and 7, the tip member 14 proximal end is distal to the longitudinal center of the balloon distal shaft section 27. However, in alternative embodiments, the tip member 14 proximal end may be located in various other locations along the length of the balloon distal shaft section 27 (not shown).

The catheter shaft will generally have the dimensions of conventional dilatation or stent deploying catheters. For coronary use, the length of the catheter 10 may be about 90 cm to about 150 cm, and is typically about 145 cm. The outer tubular member 18 has a length of about 15 cm to about 50 cm, an outer diameter (OD) of about .03 inch to about .05 inch, and an inner diameter (ID) of about .031 inch. The inner tubular member 20 has a length of about 15 cm to about 100 cm, an OD of about .024 in and an ID of about .017 in. The

inner and outer tubular members may taper in the distal section to a smaller OD or ID. Although not illustrated, the catheter shaft inner tubular member, or outer tubular member, may be made of multiple shaft sections joined together.

A method of forming a distal tip of a balloon catheter comprises

- 5 positioning a proximal end of a tip member and a distal end of a catheter shaft within a lumen of a balloon distal shaft section, so that the proximal end of the tip member is distally apart from the distal end of the catheter shaft. The balloon distal shaft section is fusion bonded to the catheter shaft and the tip member by applying heat to at least a portion of the balloon distal
- 10 shaft section, to form a balloon catheter distal tip having the tip member proximal end fusion bonded to the balloon distal shaft section and spaced distally apart from the distal end of the catheter shaft. Typically a mandrel is positioned within the inner tubular member lumen 22 and the tip member lumen 28 before the fusion bonding. In a presently preferred embodiment, a
- 15 laser is used to heat the material for fusion bonding, and laser parameters such as focal length and power are selected to provide the desired heat spread. The focal length is typically about 2.6 to about 3.25 inch, and the power is typically about 125 mw to about 170 mw for a YAG (yttrium aluminum garnet) type laser. In one embodiment, the balloon distal shaft
- 20 section is heated so that the balloon material flows into at least a part of the space between the proximal end of the tip member and the distal end of the catheter shaft. Alternatively, a removable spacer, configured to fit in the

space between the inner tubular member and the tip member, may be disposed between the distal end of the inner tubular member 21 and the proximal end of the tip member 14 during fusion bonding, or the fusion bonding heat may be controlled, such that the balloon material does not flow within the space between the inner tubular member 21 and the tip member 14.

In the embodiments illustrated in Figs. 2, 6 and 7, the outer surface of the balloon distal shaft section tapers distally to a smaller outer diameter. In one embodiment, the taper in the balloon distal shaft section 27 is formed during fusion bonding as the balloon polymeric material is heated and flows distally. Although not shown in the figures, the portion 32 of the balloon distal shaft section 27 may have a dip, i.e., a concave surface, formed as the balloon polymeric material flows into the space between the inner tubular member 27 and the tip member 14.

To the extent not discussed above, the various catheter components may be formed of conventional materials. The inner tubular member may be formed of a variety of conventional catheter shaft materials, including PEBAX, Nylon, and high density polyethylene, used alone or in blends or multilayered members. In a presently preferred embodiment, the inner tubular member includes at least a layer of PEBAX having a Shore Durometer hardness of about 60D to about 72D.

While the present invention is described herein in terms of certain

preferred embodiments, those skilled in the art will recognize that various modifications and improvements may be made to the invention without departing from the scope thereof. For example, although discussed primarily in terms of a catheter having an inner and outer tubular member, it would be

5 obvious to one of ordinary skill in the art that the catheter shaft may alternatively have a dual lumen shaft design. Moreover, although individual features of one embodiment of the invention may be discussed herein or shown in the drawings of the one embodiment and not in other

10 embodiments, it should be apparent that individual features of one embodiment may be combined with one or more features of another embodiment or features from a plurality of embodiments.